



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting  
by health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 3/31/99  
See OMB statement on reverse

FDA Use Only

Triage unit  
sequence #

Page \_\_\_\_ of \_\_\_\_

### A. Patient information

1. Patient identifier	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
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In confidence

### B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply) <input type="checkbox"/> death _____ (mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization – initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____	
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 _____ #2 _____		3. Therapy dates (if unknown, give duration from/to (or best estimate) #1 _____ #2 _____
2. Dose, frequency & route used #1 _____ #2 _____		4. Diagnosis for use (indication) #1 _____ #2 _____
6. Lot # (if known) #1 _____ #2 _____		7. Exp. date (if known) #1 _____ #2 _____
9. NDC # (for product problems only) - - -		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event)		

### D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mo/day/yr)
7. If implanted, give date (mo/day/yr)	
8. If explanted, give date (mo/day/yr)	
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	

10. Concomitant medical products and therapy dates (exclude treatment of event)

### E. Reporter (see confidentiality section on back)

1. Name & address		phone #
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		
3. Occupation		4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
or FAX to: 1-800-FDA-0178

# ADVICE ABOUT VOLUNTARY REPORTING

## Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

## Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

## Report even if:

- you're not certain the product caused the event
- you don't have all the details

## Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- therapeutic failures

## How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

## Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 to report by phone or for more information
- 1-800-822-7967 for a VAERS form for vaccines

**If your report involves a serious adverse event with a device** and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Office  
Paperwork Reduction Project (0910-0291)  
Hubert H. Humphrey Building, Room 531-H  
200 Independence Avenue, S.W.  
Washington, DC 20201

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

**Please DO NOT  
RETURN this form  
to this address.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service • Food and Drug Administration

FDA Form 3500-back

**Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

## Official Business

Penalty for Private Use \$300

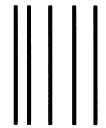
## BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

**MEDWATCH**

The FDA Medical Products Reporting Program  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20852-9787



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